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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,410	08/21/2003	Stephen H. Monroe	27432.01	7771

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,410	MONROE ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

Examiner in reviewing the IFW file noticed that the references listed on PTO 1449 (12/17/2003), sheet 2 are not in the IFW file. Examiner respectfully requests that Applicant resubmit the same and indicate publication years if not set forth in the references.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26-40 rejected under 35 U.S.C. 112, first or second paragraph, as being incomplete for omitting essential elements. See MPEP § 2172.01; MPEP § 2164.08(c). The omitted elements are: zinc. The Specification indicates that zinc is essential for wound healing (See paragraphs 0027, 0031). However, claims 26-40 do not require the presence of zinc.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Paragraph 0031 must be read in view of paragraph 0027. The disclosure cited by Applicant cannot be read to indicate that zinc is not required. If anyone of the ingredients could be used for healing then why does Specification indicate that calcium is not critical and that zinc is essential to the healing process. As such, the compositions must at least contain zinc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/11010 in view of Swerczek. (US Pat. 4,600,711), Ashcroft et al., Chen et al. and Souza et al.

WO 94/11010 discloses compositions for wound healing containing zinc, rubidium, calcium, potassium, acids and polyethylene glycol (pages 3-6, page 7, lines 1-21, page 8, lines 15-36, page 17, examples 1,3-16, claims 1-21.

Swerczek discloses a composition which greatly accelerates the healing of superficial and deep skin and muscle wounds by hastening the healing of the wound and new growth of skin and preventing bacterial and fungal infections (Column 4, lines 29-40). It is disclosed that the composition contains dextrose, buffering mixture and carrier and that the buffering mixture should provide a resulting solution having a pH of 3.0 to 6.5, such as citric acid and potassium citrate (Column 2, lines 28-68, Column 3, lines 1-3). It is disclosed that the resulting solution be viscous to inhibit drainage from the infected organs after topical application and can include polyalkylene glycols (Column 3, lines 14-19).

Ashcroft et al. disclose that chronic wound-healing states are associated with raised wound-fluid levels of MMP-2 and MMP-9, however, that wound fluid does not necessarily reflect tissue levels of proteinases (Pg. 581). It is disclosed that the measurement of MMPs included biopsies of wound tissue (Pg. 582).

Chen et al. disclose that compared to acute wounds, human chronic wounds contain markedly elevated levels of matrix metaloproteinases, while MMP inhibitors are diminished (Abstract). It is disclosed that in non-wounded skin samples, only low levels of pro and actives forms of MMP-2 were present, in normal rat wounds the amounts of both pro and active MMP-2 were elevated and that trace amounts of pro and active MMP-9 were also detected (Pg. 491). It is disclosed that ischemic wound samples showed an overall, enhancement in MMP levels compared to non-wounded skin and normal wound samples (Pg. 491). It is disclosed that although each "type" of chronic wound appears to be etiologically different, each shares one or more of the following characteristics, repeated trauma, bacterial infection and local tissue ischemia, which when prolonged lead to increased MMP production with consequent effects on matrix degradation and prevention of wound healing (Pgs. 492, 493).

Souza et al. disclose that MMP-2 and MMP-9 are inhibited by zinc sulfate (Abstract).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method of demodulating MMPs, such as MMP-2 or MMP-9, with zinc and zinc and rubidium. However, the prior art amply suggests the same as the prior art discloses a wound healing composition containing zinc, rubidium, potassium and calcium, a wound healing and infection prevention composition containing citric acid buffered to a pH range of 3.0 to 6.5, that chronic wounds are characterized by elevated levels of MMP-2 and MMP-9 and low levels of inhibitors of MMPs, whereas has normal skin contains low levels of MMP-2 and undetectable levels of MMP-9 and that zinc sulfate inhibits MMP-2 and MMP-9. As such, it would have been well within the skill of and one ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the composition would be effective in healing chronic wounds, inhibit infection, that the zinc contained in the prior art

composition would reduce the level of MMP-2 and MMP-9 thereby allowing growth of skin over the wound site and that tissues biopsies would be better able to determine effectiveness of the zinc containing composition, i.e. reduction of MMPs, such as MMP-2 and MMP-9, rather than analysis of wound fluid which does not consistently reflect tissue levels of MMPs.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992). See also In re Kotzab, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); In re Eli Lilly & Co., 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); In re Nilssen, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); and Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning). As indicated above, one of ordinary skill in the art would in view of the teachings of the prior art expect that reducing levels of MMP's in chronic wounds would be effective in treating said chronic wounds as it is the presence of the MMP's which inhibit wound healing of chronic wounds.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
January 21, 2006

JOHN PAK
PRIMARY EXAMINER
GROUP 1600